VORTRAN Medical Technology 1, Inc.

SEP 15 2011

July 25, 2011

510(k) Summary - VORTRAN APM™ K103639

1. Submitter Information	VORTRAN Medical Technology 1, Inc. 21 Goldenland Court, Suite 100, Sacramento, CA 95834
2. Contact Information	James Lee, Executive Vice President & COO TEL: (800) 434-4034 FAX: (916) 648-9751
3. Trade Name	VAPM™ (VORTRAN Airway Pressure Monitor) Kit
4. Device Classification Name	Monitor, Airway Pressure (Includes Gauge And/or Alarm)
5. Device Class	Class II
6. Regulation Number	868.2600
7. Classification Product Code	CAP
8. Classification Advisory Committee	Anesthesiology
9. Review Advisory Committee	Anesthesiology
10. Predicate Device	VAR® with VAR-Monitor™ 510(k) No.: K073261 VAR with Manometer 510(k) No.: K001430 VAR-Plus with Manometer 510(k) No.: K041473
11. Device Description	The VAPM is a battery (9 VDC) operated, portable, self-contained device that is connected to the patient via the connection tubing for monitoring cycling conditions of resuscitators such as the VORTRAN® Automatic Resuscitator.
12. Intended Use	The VORTRAN Airway Pressure Monitor (VAPM) is to be used by properly trained personnel to monitor the delivery of emergency, short term, ventilatory support to adult (using VAPM-3900 Adult Model) and/or pediatric (using VAPM-3800 Pediatric Model).
13. Substantial Equivalency Evaluation	The VAPM is substantially equivalent (SE) to legally marketed predicates like the VAR with VAR-Monitor (K073261) and other commercially available pressure manometer / alarm devices.
14. Clinical Application	The VAPM is connected to the VAR and patient via a ¼" diameter tubing through an HME/bacteria filter. There will be no flow of gas between the VAPM and VAR/patient circuit.

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15. Compliance with Performance Standards	The VAPM complies with the following INTERNATIONAL ELECTROTECHNICAL COMMISSION performance standards for medical electrical equipment, such as [i] IEC/UL-60601-1: General Requirements for Safety and; [ii] IEC 60601-1-8: – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems; [iii] IEC 60601-1-2: Collateral standard: Electromagnetic compatibility — Requirements and tests.
16. Functional Characteristics	**[a] MONITORS:** The VAPM is designed to monitor the operation of the VAR device when it is connected to a patient. The VAPM will display airway pressure like a pressure manometer and the LCD shows PIP (Peak Inspiratory Pressure) and PEEP (Positive End Expiratory Pressure) in cm-H_2O. Other respiratory functions such as Respiratory Rate (breaths per minute), inspiratory and expiratory time (seconds) and I:E Ratio are also displayed on the LCD using the same airway pressure signals. **[b] ALARMS:** An alarm function is also built into the VAPM to facilitate monitoring of the patient's respiratory function and to alert clinicians of any abnormalities. When the VAR stops cycling for a predetermined time, the VAPM will activate the NON-CYCLING ALARM. In addition, when the respiratory rate or airway pressure exceeds the preset limit, the HIGH RATE and / or HIGH PIP alarms will be activated. The VAPM has a flashing red LED and makes an audible sound when the alarm conditions display on the LCD.
17. Clinical Tests	None
18. Adverse S & E Info	None
19. Conclusion	The VAPM passed all required tests and demonstrated that it meets all predetermined acceptance criteria for applicable standards.

James Lee

[Signature]	July 25, 2011 [Dated]
James Lee [Typed Name]	Executive VP & COO [Title]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. James Lee
Executive Vice President & COO
Vorton Medical Technology 1, Incorporated
21 Golden Land Court
Sacramento, California 95834

SEP 15 2011

Re: K103639
Trade/Device Name: VORTRAN® Airway Pressure Monitor
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: September 14, 2011
Received: September 14, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

July 25, 2011

510(k) Number (if known): **K103639**

Device Name: **VORTRAN® Airway Pressure Monitor**

Indications for Use:

The VORTRAN Airway Pressure Monitor (VAPM) is to be used by properly trained personnel to monitor the delivery of emergency, short term, ventilatory support to adult (using VAPM-3900 Adult Model) and/or pediatric (using VAPM-3800 Pediatric Model).

Prescription Use : X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103639